K131423
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510(k) Summary of Safety and Effectiveness

[As required by 21 CFR 807.92]

1. Date Prepared [21 CFR807.92 (a) (1)]

NOV 07 2013

September 30th 2013

2. Submitter's Information [21 CFR807.92 (a) (1)]

Name of Sponsor: Beijing East Whale Imaging Technology Co., Ltd.

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3. Trade Name, Common Name, Classification [21 CFR807.92(a)(2)]

Trade Name: DigiArc 100AU

Common Name: G-Arm MultiScan System

Classification: Image-intensified fluoroscopic X-ray system

Product code: OXO

Classification Panel: Radiology

Device Class: II

4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

510(k) Number	K120613	K911739
Applicant	GE Healthcare Surgery	SEEMAC REISON AB CO.
Device Name	OEC 9900 Elite	SWEMAC REISON BIPLANAR 300

5. Description of the Device [21 CFR 807.92(a)(4)]

The DigiArc 100AU is a mobile digital X-ray G-Arm diagnostic system, which is intended to generate X-ray fluoroscopic image of a patient. The application includes: real-time positioning and monitoring operations in trauma surgery, orthopedics, spine surgery, and chest surgery, it is not intended to be used in interventional procedures.

There are two sets of X-ray tube assemblies and Image Intensifiers which are perpendicularly distributed on the G-Arm, acting as two sets of vertical X-ray source and receptor systems and providing fluoroscopy image of the patient. The two sets of X-ray tube assemblies and Image Intensifiers can operate simultaneously and separately.

The DigiArc 100AU includes below primary component.

Table 1- Primary components list

Component	Quantity
Control unit	1
Main monitor	2
Control monitor	1
Control panel	1
G-Arm	1
Image intensifier assembly	2
X-ray tube assembly	2
Foot switch subassembly	1
Printer (optional)	1

6. Intended Use [21 CFR 807.92(a)(5)]

The DigiArc 100AU is a mobile digital X-ray G-Arm diagnostic system, which is intended to generate X-ray fluoroscopic image of a patient. The application includes: real-time positioning and monitoring operations in trauma surgery, orthopedics, spine surgery, and chest surgery, it is not intended to be used in interventional procedures. The DigiArc 100AU permits a qualified doctor or technologist to take a range of diagnostic exposures of spinal column, chest, abdomen, extremities, and other body parts on the patients at the age of at least eighteen.

7. Technological Characteristics [21 CFR 807.92(a)(6)]

The DigiArc 100AU employs the same technological characteristics as the predicate devices except items in table 2. However, it employs the same imaging concepts and fundamental scientific technology with the predicate device and the differences do not impact the safety and effectiveness of the device.

Table 2. Major differences between subject device and predicate device

Item	OEC 9900 Elite (K120613)	SWEMAC REISON BIPLANAR 300 (K911739)	DigiArc 100AU (K131423)	Note
G-arm/C-arm	C arm	G arm	G arm	Note 1
Operation of the two sets of imaging systems	--	Operate separately only	Operate simultaneously and separately	Note 2

Note1: Image gantry of DigiArc 100AU is referred to as " G-Arm" because of its " G" shaped gantry, compare to the C-arm, there are some mechanical differences, but the differences do not impact the electrical safety and image performance of the device. And the G-arm has passed all the tests in according to IEC 60601-1:2005.

Note 2: There is no international standard special for the function of simultaneous imaging, however, the DigiArc 100AU employs the same imaging concepts and fundamental scientific technology with the predicate devices, standards (IEC 60601-1: 2005 & IEC 60601-1-2:2007 & IEC 60601-1-3:2008 & IEC 60601-2-28:2010 & IEC 60601-2-54:2009) that apply to predicate devices also apply to the DigiArc 100AU, the DigiArc 100AU has passed all the tests in according to those standards which ensure that there is no safety and performance issue rasied. Besides, software validation and images assessment for simultaneous imaging have been done by the manufacturer, and the results demonstrate that the subject device meet the requirement of intended use and clinical use.

8. Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92(b)(2)]

Results of performance and compliance testing conducted on DigiArc 100AU indicates conformance to all applicable standards recognized by FDA for this device.

Testing result from non-clinical & clinical demonstrates that the subject device

DigiArc 100AU is as safe and effective as the predicate devices.

Non-clinical testing:

The subject device has been tested to compliance to the following safety and performance standards:

IEC 60601-1: 2005

IEC 60601-1-2:2007

IEC 60601-1-3:2008

IEC 60601-2-28:2010

IEC 60601-2-54:2009

And also the subject device meets the provisions of Digital Imaging communications in Medicine (DICOM)

Clinical testing:

Clinical images evaluation was performed for each X-Ray generator and image intensifier which was considered as a critical component of verification and validation.

9. Conclusion [21 CFR 807.92(b) (3)]

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the non-clinical & clinical testing result and relative information provided in this premarket notification, we concludes that DigiArc 100AU is substantially equivalent to predicate devices with regard to safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 7, 2013

Beijing East Whale Imaging Technology Co., Ltd.
% Better Li
No. 2 Workshop Bldg 2, No. 9 KeChuang 2 Street
Beijing Economy Technology Exploitation Section
Beijing, 100023
CHINA

Re: K131423
Trade/Device Name: G-Arm MultiScan System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OXO
Dated: October 14, 2013
Received: October 22, 2013

Dear Better Li:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): ~~In process~~ K131423

Device Name: G-Arm MultiScan System

Indications for Use: The DigiArc 100AU is a mobile digital X-ray G-Arm diagnostic system, which is intended to generate X-ray fluoroscopic image of a patient. The application includes: real-time positioning and monitoring operations in trauma surgery, orthopedics, spine surgery, and chest surgery, it is not intended to be used in interventional procedures. The DigiArc 100AU permits a qualified doctor or technologist to take a range of diagnostic exposures of spinal column, chest, abdomen, extremities, and other body parts on the patients at the age of at least eighteen.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

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